

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 27 OCT 2005

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| Applicant's or agent's file reference 278-1.B.WO | FOR FURTHER ACTION | | See Form PCT/PEA/416 |
| International application No. PCT/CH2004/000466 | International filing date (day/month/year) 23.07.2004 | Priority date (day/month/year) 24.07.2003 | |
| International Patent Classification (IPC) or national classification and IPC A61F2/46 | | | |
| Applicant ECHEVERRI, SANTIAGO | | | |

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☒ sent to the applicant and to the International Bureau a total of 2 sheets, as follows:
 - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

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| Date of submission of the demand 20.05.2005 | Date of completion of this report 26.10.2005 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Buchmann, G Telephone No. +49 89 2399-2288  |

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/CH2004/000466

Box No. 1 Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ International search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-12 received on 20.05.2005 with letter of 18.05.2005

Drawings, Sheets

1/16-16/16 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/CH2004/000466

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-11 |
| | No: Claims | 12 |
| Inventive step (IS) | Yes: Claims | 1-11 |
| | No: Claims | 12 |
| Industrial applicability (IA) | Yes: Claims | 1-12 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following document/s/:

D3: US-B1-6 395 005 (LOVELL TIMOTHY PATRICK) 28 May 2002 (2002-05-28)

Independent Claim 1

The document D3 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (see column 5, line 7 - column 6, line 65, column 9, lines 8-45):
A guide (70, 180) for a surgical instrument, comprising a shaft (120, 222), instrument fixing means (250) for fixing the guide to an instrument, and a frame (120, 254) situated between said shaft and said instrument fixing means. At the distal end of the shaft (120, 222), pointing means (122, 234) are provided.

The subject-matter of claim 1 differs from this known guide in that it comprises orientation means, distinct from the shaft, which are adapted to define a reference plane.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as to provide a guide which improves accuracy of implantation.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
None of the documents cited in the international search report discloses or fairly suggests a guide according to claim 1, comprising an orientation means defining a reference plane.

Claims 2-11 are dependent on claim 1 and as such also meets the requirements of the PCT with respect to novelty and inventive step.

Independent Claim 12

The subject-matter of claim 12 is not new in the sense of Article 33(2) PCT:

Claim 12 defines a calibrating apparatus which is suitable for calibrating a guide and an instrument as defined in claim 1. According to the Guidelines C-III, 4.8, this does not include any features of the guide or the instrument as defined in claim 1.

Hence, claim 12 defines only a calibrating apparatus, comprising angle reproducing means. Such an apparatus, however, is clearly not new, because any angle gauge can be regarded as an angle reproducing means and also as an calibrating apparatus.

A combination of a guide according to claim 1 and a calibrating apparatus would fulfill the requirements of the PCT.

Re Item VII

Certain defects in the international application

The document D3 is not identified in the description and the relevant background art disclosed therein is not discussed (Rule 5.1(a)(ii) PCT).

The passage on page 13, lines 11-18 refers in an unclear way to the spirit of invention (PCT Guidelines, III-4.3(a)).

Re Item VIII

Certain observations on the international application

Claims 11 and 12 lack clarity (Art. 6, PCT) for the following reasons:

Claims 11 and 12 refer to the measurement of an angle between ASIS and HJC. However, ASIS and HJC appear to be two points. It is not clear, how and angle could be measured between two points.

Claims

1. Guide (2) for surgical instrument (4,37) such as an acetabular prosthetic cup
5 instrument, said guide (2) comprising a shaft (8), instrument fixing means (11) for
fixing said guide (2) to a surgical instrument (4,37) and a frame (35) situated
between said shaft (8) and said instrument fixing means (11), **characterized by**
the fact that it furthermore comprises pointing means (12,38) situated at the shaft
10 (8) distal end and orientation means (6), distinct from the shaft (8), which are
adapted to define a reference plane.
2. Guide (2) according to claim 1 wherein said pointing means comprise a pair of
parallel shafts (12) which are oriented at an angle with respect to the shaft (8)
15 direction.
3. Guide (2) according to claim 1 wherein said pointing means comprise a laser
beam (38).
4. Guide according to anyone of claims 1 to 3 wherein said orientation means (6) are
20 adjustable.
5. Guide according to claim 4 wherein said orientation means (6) comprise two
bubble levels (9,10).
6. Guide according to claim 5 wherein the first bubble level (9) is adapted for
25 orientating an instrument (4,37) fixed to said guide (2) with respect to a right hip
and wherein the second bubble level (10) is adapted for orientating said
instrument (4,37) with respect to a left hip.
7. Guide according to anyone of claims 1 to 6 wherein said instrument fixing means
30 (11) are adapted to allow a quick fixation or release of the guide (2) to/from the
instrument (4,37).
8. Combination of a guide (2) according to anyone of the previous claims together
35 with an acetabular prosthetic cup instrument (4,37) comprising a shaft and with a

handle at its proximal end and with a distal end adapted for receiving either a reamer or a cup positioner.

5 9. Combination of a guide (2) according to anyone of the previous claims 1 to 7 together with a pelvic positioner (17), said pelvic positioner (17) comprising two arms (20) with respective feelers (22) and orientation means (19).

10 10. Combination of a guide (2) according to anyone of the previous claims 1 to 7 together with a pelvic orientation witness (3), said pelvic orientation witness comprising pelvic fixing means (15) for fixing said pelvic orientation witness (3) to the pelvis (13) and orientation means (16).

15 11. Combination of a guide (2) according to anyone of the previous claims 1 to 7 together with an angle measuring device for measuring the angle between ASIS (Anterio Superior Iliac Spine) and HJC (Hip Joint Center).

20 12. Calibrating apparatus (23) for calibrating a guide (2) and an instrument (4) as defined in anyone of previous claims 1 to 8, said calibrating apparatus (23) comprising angle reproducing means for reproducing the angle between ASIS and HJC.